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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,808	01/27/2000	BJORN H. LINDQVIST	100084.410	2109

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/331,808

Applicant(s)

LINDQVIST ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/20/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-29,31,34-36,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-29,31,34-36,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 21, 22, 24-29, 31, 34-36 and 39-40 are pending in the application and under consideration.

Claims 1-20, 23, 30, 32-33 and 37-38 have been cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

Claim 31 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claimed isolated complex comprising a DNA molecule covalently bound to a cis-acting DNA binding protein does not have a specific or well-established utility per se. The specification does not describe a specific utility for said complex.

Claim 31 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See the rejection above.

Response to Arguments

Applicants state that with the amendment to claim 31, this rejection should be withdrawn. However, the amended claim is rejected, as above.

Claim Objections

Claim 31 is objected to because of the following informalities: it recites "comprises" and "comprising" in claim 31, line 3. Also, at line 5, "that is said..." is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 102

Response to Arguments

In view of the amendments to claim 31 and cancellation of claim 32, the rejection under 35 USC 102 over Liu is withdrawn.

Claims 21, 22, 24, 26, 27, 28, 31, 34-36 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Maruyama et al (USP 5,627,024) for reasons advanced in the last Office action.

Response to Arguments

Applicants urge that Maruyama et al relates to bacteriophage. In bacteriophage display technology, a protein is expressed in such display technology. In that it is displayed on the phage particle surface. As with any other virus, bacteriophage package phage DNA within the phage particle. Thus, a protein that is displayed on the bacteriophage surface is "associated" with its encoding DNA, which forms part of the DNA that is packaged within the phage particle. It is not, however, covalently bound to its encoding DNA. The rejection appears to be based on the reference in Maruyama et al to "cis." In the citation, cis is defined as "when the phage genome contains a second cistron for expression of heterosubunits", the cistron being defined as a "sequence of nucleotides in a DNA molecule coding for an amino acid residue sequence and including upstream and downstream DNA expression control elements" (see the definitions in column 6 of Maruyama et al). The reference to "cis" in Maruyama et al has nothing whatsoever to do with cis-acting proteins of the instant invention. In the present invention, when the cis-acting DNA binding protein is expressed, it binds covalently to its own encoding DNA. Nothing in Maruyama et al teaches this type of DNA:protein binding.

In response, applicants does not seem to controvert that

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the method of Murayama is the same as the instant method and acknowledge as above, that the protein displayed on the bacteriophage surface is "associated" with its encoding DNA. Applicants' attention is directed to Maruyama's disclosure at col. 16, lines 10-45 which discloses the formula of a fusion of the polypeptide to its DNA encoding sequence. At line 20, it states that the preferred polypeptide comprises a preselected polypeptide operatively linked at its amino terminus to the lambdoid matrix anchor polypeptide. At line 40 operatively lined means that polypeptide fragments have been covalently linked. Also, at col. 2, lines 29-34, it states "the multimeric polypeptides and the genes which encode the polypeptides are thus physically linked during the assembly stage of the phage replication cycle." At col.8, lines 62-63, it discloses that lambdoid phage particles are about half protein and half DNA (similar to the instant bacteriophage (Φ X174) that contains the cis acting DNA protein P2A in its genome.) Thus, the disclosure of Murayama teaches covalent linkage between the components of the methods. Even assuming that Murayama does not positively recite (but, at least suggests such covalent binding), the mere discovery of an unappreciated benefit which is inherent in a practice already utilized by a prior art is not a patentable

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discovery. G.D. co. v. Jewel Incandescent Lamp Co. 326 US 242, 66. S. Ct. 81, 90 C. Ed. 43 67 USPQ 155 (1945).

It is further unclear how the disclosure of Murayama of a cis phage encoding genome would have nothing to do with the cis-acting protein of the instant invention. Murayama discloses at col. 24, lines 14-17 that a DNA expression vector provides a system for inserting translatable DNA sequences to produce a cistron capable of expressing fusion polypeptide. This cistron for expression of the different polypeptide can be located in cis or trans relative to the fusion protein cistron, as disclosed at col. 28, lines 62-64. See also col. 23, lines 3-25. That is, that the protein translated by DNA is a cis-acting DNA protein.

Claim Rejections - 35 USC § 103

Claims 21, 22, 24-29, 31, 34-36 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama in view of Liu et al (Virology, 1996) for reasons set forth in the last Office action.

Response to Arguments

Applicants assert that nothing in Liu et al would have cured the fundamental failings of Maruyama et al. Furthermore, given the differences between the teachings of Liu et al

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(detailed above) and those of Maruyama et al, no justification for the combination is seen. The approach used in Maruyama et al requires the production of phage particles. The use of the protein of Liu et al would be expected to interfere with the ability of bacteriophage proteins to package DNA.

In response, Liu is employed for the use of P2A that is known to be present in bacteriophage the prototype of which is the Φ X174. Murayama suggested several types of bacteriophages species that can be used in the instant method. It would be within the ordinary skill in the art at the time the invention was made to determine which of these bacteriophage species would be a P2A protein since Liu suggests that the bacteriophage Φ X174 is only a prototype.

No claim is all lowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS**

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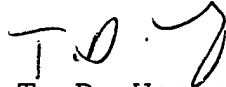
of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 2, 2005